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Erectile Implants in Female-to-Male Transsexuals: Our Experience in 129 Patients

Piet B. Hoebeke [a,*], *Karel Decaestecker* [a], *Matthias Beysens* [a], *Yasmin Opdenakker* [a], *Nicolaas Lumen* [a], *Stan M. Monstrey* [b]

[a] *Department of Urology, Ghent University Hospital, Ghent, Belgium*
[b] *Department of Plastic Surgery, Ghent University Hospital, Ghent, Belgium*

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Abstract

Background: The combination of a neourethra and erection prosthesis in a single neophallus in the female-to-male transsexual remains a challenge. No good data are available on this subject.
Objective: To report the outcome in 129 female-to-male transsexuals with a neophallus after the implantation of an erectile prosthesis.
Design, setting, and participants: From March 1996 until October 2007, 129 female-to-male transsexuals with a neophallus underwent the implantation of an erectile prosthesis. The mean follow-up was 30.2 mo (range: 0–132 mo).
Intervention: A Dynaflex prosthesis was implanted initially in 9 patients, a three-piece hydraulic device (AMS CX or AMS CXM) in 50 patients, and a CX Inhibizone, Ambicor, and Coloplast/Mentor prosthesis in 17, 47, and 6 patients, respectively.
Measurements: Data on outcome in these patients were retrospectively evaluated.
Results and limitations: Of 129 patients, 76 patients (58.9%) still have their original implant in place. Fifty-three patients (41.1%) needed to undergo either removal or revision of the prosthesis due to infection, erosion, dysfunction, or leak. Forty-one patients underwent a replacement of the prosthesis, nine needed a second revision, five needed a third revision, and one patient needed a fourth revision of prosthesis. Malposition of prosthesis was corrected by surgical repositioning so that removal or revision could be avoided. Of 185 prostheses used in 129 patients, 108 (58.4%) still remain in place, with a total infection rate of 11.9%, a total protrusion rate of 8.1%, a total prosthesis leak rate of 9.2%, a total dysfunction rate of 13%, and a total malposition rate of 14.6%.

The period of follow-up in the more recent types of prostheses (Ambicor, Coloplast/Mentor) is much shorter; therefore, comparison with earlier types is difficult to make.
Conclusions: Despite high complication rates, implantation of a hydraulic erectile prosthesis remains the best option for achieving the possibility of sexual intercourse in female-to-male transsexuals.

* Corresponding author. Ghent University Hospital, Urology, De Pintelaan 185, Ghent, 9000, Belgium.
Tel. +3192402276; Beeper: 3192402281; Fax: +3192403889.
E-mail address: piet.hoebeke@ugent.be (P.B. Hoebeke).

1. Introduction

The final step in the multidisciplinary approach of gender reassignment therapy in female-to-male transsexuals consists of the construction of a neophallus [1]. This procedure allows the patient to void while standing. Although voiding while standing is a priority for most female-to-male transsexuals [2], most patients want to use the neophallus for sexual experience after they are accustomed to their new voiding abilities. The main limiting factor is that there is no good substitute for the unique erectile tissue of the penis. Different techniques have been used to obtain rigidity in the neophallus, but often, they resulted in complications and failure [3].

In 1973, Scott et al introduced the first inflatable erectile prosthesis [4]. Puckett and Montie were the first to use this technique in a female-to-male transsexual in 1977 [5]. We started to perform this procedure in March 1996 with the one-piece Dynaflex hydraulic prosthesis (American Medical Systems, Minnetonka, MN, USA). After 2 yr, the Dynaflex prosthesis was no longer available, and so we implanted a three-piece CX, CXM, or CX Inhibizone hydraulic system (American Medical Systems) [6]. In 2003, the two-piece Ambicor (American Medical Systems) and Coloplast/Mentor (Mentor Corporation, Santa Barbara, CA, USA) systems were also introduced.

2. Patients and methods

From March 1996 until October 2007, 129 out of a group of 182 female-to-male transsexuals with a neophallus underwent the implantation of a hydraulic erectile prosthesis. The mean age at the time of operation was 34.1 yr (range: 17–53 yr). All patients had already undergone a phalloplasty, using a free sensate radial forearm flap, at an average age of 31.9 yr (range: 15–52 yr). Our technique of phalloplasty has been previously described [1]. Implantation of the hydraulic prosthesis was done as a secondary or tertiary procedure, with a mean interval of 23 mo (range: 9–127 mo) between phalloplasty and prosthesis implantation. Implantation of an erectile prosthesis is only performed when the phallus is properly healed and has been endowed with protective sensation. This protective sensation was measured by methods formerly discussed in an earlier publication [7].

For implantation of the erectile prosthesis, we use the same aseptic technique as in implantation of an erectile prosthesis in an impotent patient. The skin is shaved just before the patient goes to the operating room. In the operating room, the skin is rubbed with Iso-Betadine solution for 5 min, and disinfection of the skin is performed using iodium in alcohol. Antibiotic prophylaxis is given during the operation, lasting until 1 d after the operation. Cefazolin 3×1 g is used routinely.

A transurethral catheter is placed. A parascrotal incision is performed, and dissection under the urethra on the pubic bone is done until over the midline. One or two tracts are dilated in the phallus by use of Hegar dilators. After the tract inside the phallus is dilated, the length of the cylinder is determined by measuring the tract. If only one cylinder is used, the other cylinder is removed and deactivated by use of a deactivation device. The prosthesis is inserted by using the Furlow introducer. Until February 2006, the prosthesis was covered by a Dacron vascular prosthesis. the base which was fixed to the pubic bone. This has since been abandoned because of high rates of prosthesis dysfunction due to erosion. Nowadays, the base of the cylinder covered by a rear tip extender is fixed using a nonresorbable suture. For the pump, a scrotal pouch is made and the pump inserted. When three-piece devices were implanted, the reservoir was placed in a paravesical space developed from the parascrotal incision along the inguinal canal. In most patients, a testicular implant was done at the time of the erectile implant in the contralateral scrotal pouch using a new incision at the neck of the scrotum.

3. Results

The following protheses were initially implanted: a Dynaflex one-cylinder (standard) prosthesis in 9 patients; an AMS three-piece hydraulic device (AMS CX or AMS CXM) in 50 patients (37 with one cylinder, 13 with two cylinders); an AMS CX Inhibizone prosthesis in 17 patients (13 with one cylinder, 4 with two cylinders); an AMS Ambicor prosthesis in 47 patients (22 with one cylinder, 25 with two cylinders); and a Coloplast/Mentor prosthesis in 6 patients (all with two cylinders) (Table 1). The decision on the number of cylinders implanted was made at the beginning of surgery based on the girth of the phallus and the possibility of dilating two pockets without damaging the urethra. With the observation of unaesthetic outcomes due to asymmetry in the final position of the cylinders, the two-cylinder option was no longer proposed to the patients. The decision to change the type of prosthesis was based on the fact that the prosthesis was no longer commercialised for Dynaflex and on the observation of a high number of leaks for the AMS CX and AMS CXM. An example of a phallus with prosthesis implanted is shown in Fig. 1. An example of an unaesthetic outcome with two cylinders is shown in Fig. 2.

The mean period of follow-up was 56.5 mo (range: 6–132 mo) for the Dynaflex group, 42.3 mo (range: 0–118 mo) for the three-piece hydraulic device group, 27.7 mo (range: 0–70 mo) for the CX Inhibizone group, 11.85 mo (range: 0–46 mo) for the Ambicor group, and 21.5 mo (range: 3–43 mo) for the Coloplast/Mentor group (Table 2).

Of 129 patients, 41 needed a replacement of the prosthesis due to complications, 9 needed a second revision, 5 needed a third revision, and 1 patient needed a fourth revision of the prosthesis. A total of 185 prostheses was used in 129 patients: 15 Dynaflex (standard one cylinder); 69 AMS three-piece hydraulic devices (52 with one cylinder, 17 with two cylinders); 34 AMS CX Inhibizone (28 with one cylinder, 6 with two cylinders); 59 AMS Ambicor (32 with

Table 1 – Prostheses used in 129 patients initially

Type of prosthesis, no. of cylinders	*n*	%
Dynaflex, one cylinder	9	7.0
AMS three-piece hydraulic device group (CX/CXM), one cylinder	37	28.7
AMS three-piece hydraulic device group (CX/CXM), two cylinders	13	10.1
AMS CX Inhibizone, one cylinder	13	10.1
AMS CX Inhibizone, two cylinders	4	3.1
AMS Ambicor, one cylinder	22	17.1
AMS Ambicor, two cylinders	25	19.4
Coloplast/Mentor, two cylinders	6	4.7
Total	129	100

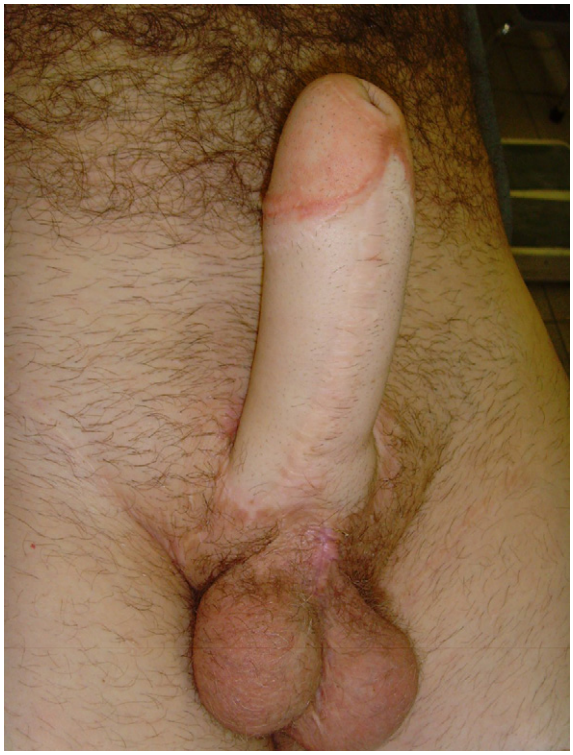

Fig. 1 – Phallus with implant.

Fig. 2 – Unaesthetic outcome with two cylinders.

one cylinder, 27 with two cylinders); and 8 Coloplast/Mentor (all with two cylinders) hydraulic rigidity prostheses (Table 3).

Of the 129 patients, 76 patients (58.9%) still have their original implant in place. Fifty-three patients (41.1%) needed to undergo either removal or revision, which is defined as a surgical replacement of a part of the original prosthesis or a replacement of a total prosthesis due to infection, erosion, dysfunction, or leak. A malposition of the prosthesis was corrected by surgical reposition of the prosthesis so that the original implant could remain in place and, thus, is not counted as removal or revision. Of 185 prostheses used in 129 patients, 108 (58.4%) still remain in place, with a total infection rate of 11.9% (22 prostheses), a total protrusion rate of 8.1% (15), a total prosthesis leak rate of 9.2% (17), a total dysfunction rate of 13% (24), and a total malposition rate of 14.6% (27) (Table 4, Fig. 3).

In the Dynaflex group, one (6.7%) case of leakage and one (6.7%) case of infection were seen, but the main cause of removal was dysfunction (8 cases, or 53.3%). Malposition was seen in two (13.3%) cases.

In the Ambicor group, nine (15.3%) cases of infection and five (8.5%) cases of protrusion were observed. There were no cases of dysfunction or leakage. In this group, seven (11.9%) patients needed repositioning of their prosthesis for malposition.

In the AMS three-piece hydraulic device group, 38 of 69 patients needed explantation of their prosthesis due to infection, protrusion, leakage, or dysfunction in, respectively, 9 (13.0%), 7 (10.1%), 12 (17.4%), and 10 (14.5%) cases. There were also 14 (20.3%) cases of malposition.

In the group of patients with a Coloplast/Mentor prosthesis, four (50%) out of eight patients needed prosthesis removal due to one (12.5%) case of infection, one (12.5%) case of leakage, and two (25%) cases of dysfunction. One (12.5%) prosthesis needed to be repositioned.

In the CX Inhibizone group, 12 (35.3%) out of 34 patients underwent prosthesis explantation due to two (5.9%) cases of infection, three (8.8%) cases of leakage, four (11.8%) cases of dysfunction, and three (8.8%) cases of protrusion. In this group, there were three (8.8%) cases of malposition.

Table 2 – Follow-up sorted by type of prosthesis

Type of prosthesis	*n*	Date of first implantation	Follow-up, mo				
			Mean	Minim	Max	Range	SD
Dynaflex	15	8 March 1996	56.53	6	132	126	44.00
AMS three-piece hydraulic device group (CX/CXM)	69	4 December 1997	42.29	0	118	118	27.69
AMS CX Inhibizone	34	30 November 2001	27.74	0	70	70	16.80
AMS Ambicor	59	5 December 2003	11.85	0	46	46	10.05
Coloplast/Mentor	8	27 October 2003	21.5	3	43	40	18.00
Total	185	8 March 1996	30.16	0	132	132	27.37

Table 3 – Total count of prostheses used in 129 patients

Type of prosthesis, no. of cylinders	*n*	%
Dynaflex, one cylinder	15	8.1
AMS three-piece hydraulic device group (CX/CXM), one cylinder	52	28.1
AMS three-piece hydraulic device group (CX/CXM), two cylinders	17	9.2
AMS CX Inhibizone, one cylinder	28	15.1
AMS CX Inhibizone, two cylinders	6	3.2
AMS Ambicor, one cylinder	32	17.3
AMS Ambicor, two cylinders	27	14.6
Coloplast/Mentor, two cylinders	8	4.3
Total	185	100.0

In Table 5, the complications are sorted by number of cylinders used for each prosthesis. In Table 6, they are sorted by length of the cylinders used.

In the Dynaflex group, only three (20%) prostheses still remain in place, with a mean survival of 63.9 mo. In the AMS three-piece hydraulic device group, the CX Inhibizone group, Coloplast/Mentor group, and Ambicor group, respectively, 31 (44.9%), 23 (67.6%), 4 (50%), and 47 (79.7%) prostheses still remain in situ. The mean survival rates were 55.7, 39.9, 28.6, and 36.2 mo, respectively (Tables 7 and 8). The median survival could not be calculated for all types of prostheses, due to differences in terms of follow-up (see Table 2).

Kaplan-Meier survival analysis showed a survival rate at 25 mo of 78.8% for Dynaflex, 75% for the three-piece hydraulic device group, 72.5% for CX Inhibizone, 78% for Ambicor, and 72% for Coloplast/Mentor. The survival rate at 50 mo was 51.3% for Dynaflex, 55% for the AMS three-piece hydraulic device group, and 58.8% for CX Inhibizone (Fig. 3).

4. Discussion

In our study, we retrospectively evaluated the outcome in 129 female-to-male transsexuals after implantation of a hydraulic erectile prosthesis. Because the groups in this study were too small, statistical significance could not be attained; however, this is the largest series of female-to-male transsexual patients with a hydraulic erectile device ever reported. Average follow-up in these patients was 44.3 mo (range: 0–139 mo) (Fig. 4).

Reports in the literature are poor, with only a few studies with small numbers of patients published. The first report of implantation of a hydraulic system dates from 1978 by Puckett and Montie [5]. In 1993, Levine et al reported excellent results in four patients [8]. In 1994, Jordan et al assessed different hydraulic systems for

Table 4 – Complications sorted by different types of prostheses

Type of prosthesis	*n*	Infection, no. (%)	Protrusion, no. (%)	Leak, no. (%)	Dysfunction, no. (%)	Malposition, no. (%)	Other, no. (%)
Dynaflex	15	1 (6.7)	0 (0.0)	1 (6.7)	8 (53.3)	2 (13.3)	1 (6.7)
AMS three-piece hydraulic device group (CX/CXM)	69	9 (13.0)	7 (10.1)	12 (17.4)	10 (14.5)	14 (20.3)	1 (1.4)
AMS CX Inhibizone	34	2 (5.9)	3 (8.8)	3 (8.8)	4 (11.8)	3 (8.8)	0 (0.0)
AMS Ambicor	59	9 (15.3)	5 (8.5)	0 (0.0)	0 (0.0)	7 (11.9)	0 (0.0)
Coloplast/Mentor	8	1 (12.5)	0 (0.0)	1 (12.5)	2 (25.0)	1 (12.5)	1 (12.5)
Total count	185	22 (11.9)	15 (8.1)	17 (9.2)	24 (13.0)	27 (14.6)	3 (1.6)

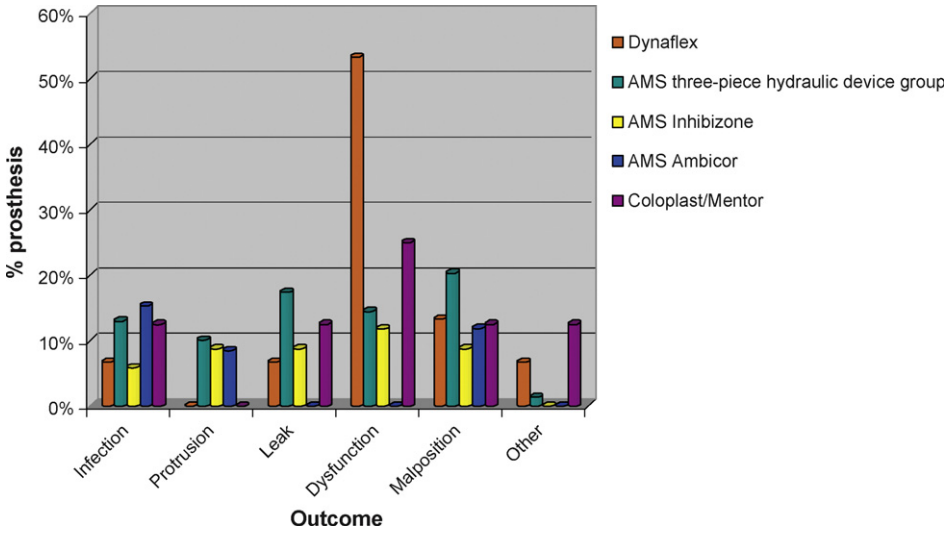

Fig. 3 – Outcome sorted by type of prosthesis.

Table 5 – Complications sorted by number of cylinders used in different types of prostheses

Type of prosthesis, no. of cylinders	*n*	Infection, no. (%)	Protrusion, no. (%)	Leak, no. (%)	Dysfunction, no. (%)	Malposition, no. (%)	Other, no. (%)
Dynaflex, one cylinder	15	1 (6.7)	0 (0.0)	1 (6.7)	8 (53.3)	2 (13.3)	1 (6.7)
AMS three-piece hydraulic device group (CX/CXM), one cylinder	52	8 (15.4)	3 (5.8)	9 (17.3)	7 (13.5)	10 (19.2)	1 (1.9)
AMS three-piece hydraulic device group (CX/CXM), two cylinders	17	1 (5.9)	4 (23.5)	3 (17.6)	3 (17.6)	4 (23.5)	0 (0.0)
AMS CX Inhibizone, one cylinder	28	2 (7.1)	3 (10.7)	3 (10.7)	3 (10.7)	3 (10.7)	0 (0.0)
AMS CX Inhibizone, two cylinders	6	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)
AMS Ambicor, one cylinder	32	3 (9.4)	3 (9.4)	0 (0.0)	0 (0.0)	2 (6.2)	0 (0.0)
AMS Ambicor, two cylinders	27	6 (22.2)	2 (7.4)	0 (0.0)	0 (0.0)	5 (18.5)	0 (0.0)
Coloplast/Mentor, two cylinders	8	1 (12.5)	0 (0.0)	1 (12.5)	2 (25.0)	1 (12.5)	1 (12.5)
Total count	185	22 (11.9)	15 (8.1)	17 (9.2)	24 (13.0)	27 (14.6)	3 (1.6)

Table 6 – Complications sorted by length of cylinders used

Length of cylinder	*n*	Infection, no. (%)	Protrusion, no. (%)	Leak, no. (%)	Dysfunction, no. (%)	Malposition, no. (%)	Other, no. (%)
12 cm	34	4 (11.8)	2 (5.9)	5 (14.7)	3 (8.8)	6 (17.6)	0 (0.0)
13 cm	1	1 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
14 cm	40	4 (8.9)	6 (13.3)	0 (0.0)	6 (13.3)	8 (17.8)	1 (2.2)
15 cm	58	4 (6.9)	4 (6.9)	9 (15.5)	9 (15.5)	7 (12.1)	1 (1.7)
16 cm	32	7 (21.9)	2 (6.2)	3 (9.4)	5 (15.6)	3 (9.4)	1 (3.1)
18 cm	9	2 (22.2)	1 (11.1)	0 (0.0)	0 (0.0)	1 (11.1)	0 (0.0)
20 cm	1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total count	180	22 (12.2)	15 (8.3)	17 (9.4)	23 (12.8)	25 (13.9)	3 (1.7)

different indications, including penile trauma, intersex, and transsexualism [9]. The success rate in eight patients was 60%. In 2003, we reported the results of prosthesis implantation in 35 female-to-male transsexuals at our centre [6]. To our knowledge, these are the three largest series of hydraulic erectile devices published to date.

Table 7 – Number of prosthesis removals

Type of prosthesis	*n*	No. removed	Prostheses in situ	
			No.	%
Dynaflex	15	12	3	20.0
AMS three-piece hydraulic device (CX/CXM)	69	38	31	44.9
AMS CX Inhibizone	34	11	23	67.6
AMS Ambicor	59	12	47	79.7
Coloplast/Mentor	8	4	4	50.0
Total count	185	77	108	58.4

Table 8 – Survival sorted by type of prosthesis

Type of prosthesis	Mean survival, mo	Median survival, mo
Dynaflex	63.9	53.0
AMS three-piece hydraulic device (CX/CXM)	55.7	62.0
AMS CX Inhibizone	39.9	†
AMS Ambicor	36.2	†
Coloplast/Mentor	28.6	39.0
Total count	58.9	53.0

† Could not be calculated.

Because these are the only data available on this subject, it is only possible to compare our results to studies on the subject of prosthesis implantation in male patients; however, there are some important differences. First, there is no serviceable crus penis or corpora cavernosa roots in female-to-male transsexuals. This may contribute to a higher risk of malposition. Second, the tissue of the constructed neophallus is totally different from the tissue in a normal male penis. This may cause a higher risk of prosthesis protrusion and infection. Third, the prosthesis is implanted in an area that was previously operated on extensively, causing a lot of scar tissue, which is less vascularised and, thus, probably the origin of a higher infection rate. Finally, most female-to-males transsexuals are young (mean age: 34.1 yr), so one may presume that they are sexually more active than older males who show erectile dysfunction. This may lead to more mechanical failure of prostheses.

For all types of prostheses, there is a higher rate of infection in our study compared with infection rates in males. In Dynaflex, we see 6.7% of infection, whereas a study with males shows 4.8% [10]. For three-piece models, 13.0% infection is seen in contrast with 3.2% in males [11]. Ambicor shows an even higher rate of infection, with 15.3% in our study versus 4.6% in males [12]. These figures can by explained by the difference in tissue. CX Inhibizone prostheses, which are coated with an antibiotic layer, show lower rates of infection (5.9% vs 13.0% in noncoated three-piece models). This trend was also seen in studies with

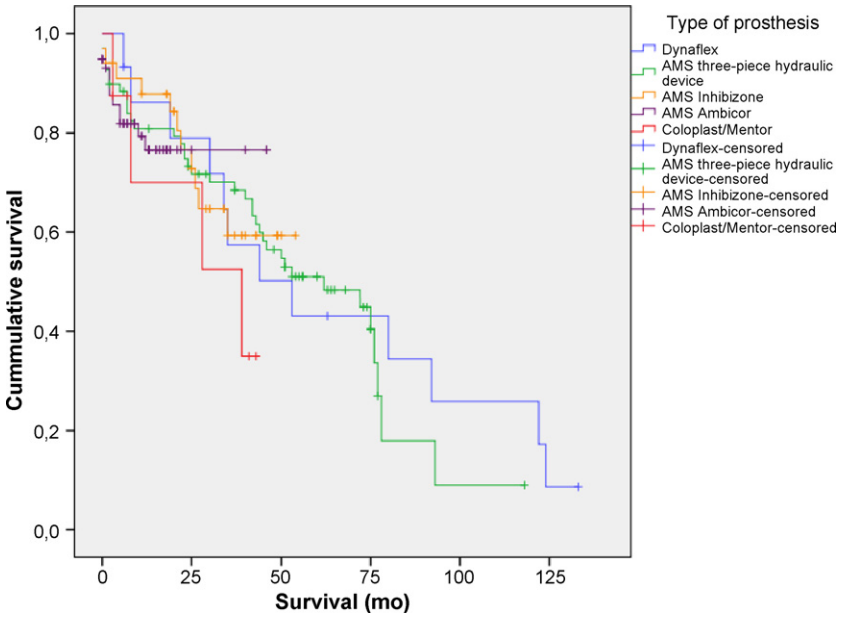

Fig. 4 – Kaplan-Meier survival plot (all types of prostheses).

males: 0.68% infection in CX Inhibizone versus 1.61% infection in controls with noncoated three-piece prostheses [13].

Mechanical failure is also higher in our patients: 14.5% dysfunction and 17.4% leakage in three-piece prostheses in our study versus 4.3% and 10.8% in males [11]. Mechanical failure of Dynaflex was also high in studies with men: Wilson et al saw 26.2% mechanical failure after 2.6 yr [14]. In our study, there was 60% failure after 4.71 yr. High rates of mechanical failure in Dynaflex prostheses can be explained by the greater length of follow-up (mean of 56.53 mo). Little mechanical failure was seen in Ambicor, due to a very short follow-up (mean of 11.85 mo). Studies with men showed 2.3% leakage in Ambicor after a mean follow-up period of 43.4 mo [12].

5. Conclusions

Despite these high complication rates, implantation of a hydraulic erectile prosthesis remains the best option for achieving the possibility of voiding while standing as well as sexual intercourse in female-to-male transsexuals after phalloplasty. The choice of device cannot be decided based on the data presented in this paper; however, trends seem to reflect that two-piece devices are better than three-piece devices.

Author contributions: Piet Hoebeke had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Hoebeke.
Acquisition of data: Beyssens, Opdenakker.
Analysis and interpretation of data: Beyssens, Opdenakker, Lumen.
Drafting of the manuscript: Beyssens, Opdenakker, Hoebeke.
Critical revision of the manuscript for important intellectual content: Lumen, Monstrey, Hoebeke.
Statistical analysis: Lumen, Beyssens, Opdenakker.
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Editorial Comment on: Erectile Implants in Female-to-Male Transsexuals: Our Experience in 129 Patients

Sava V. Perovic
Department of Urology, School of Medicine – University of Belgrade, Serbian Academy of Sciences and Arts, Belgrade, Serbia

The article is the largest retrospective study of female-to-male transsexuals with implantation of inflatable prosthesis into neophallus [1]. Use of 185 implants in 129 neopenises clearly reflects that we are far from a perfect solution that enables the sexual lives of transgender patients. The authors are to be congratulated for great and demanding work.

Some issues, however, should be addressed. Capsule formation around erectile implant is a very long process that often results in the creation of a weak capsule with poor resistance to infection or with protrusion. Covering of cylinders with a vascular graft may prevent this problem, but risk of implant mechanical failure probably increases due to the rubbing of cylinders with the graft during sexual intercourse. We used vascular or mesh graft successfully for covering of the top of the prosthesis, with the aim of preventing protrusion or malposition of the cylinders. Thus, when considering use of a graft, one must take into account its advantages and disadvantages.

Number and size of implanted cylinders reflect neophallic size, which was typically only 10–12 cm long and very thin. Maybe earlier prosthesis implantation after total phalloplasty could prevent retraction of the fasciocutaneous flap, which normally happens with time.

Although the urethra was not a topic of this article, it is useful to point out that long-term, unpublished data (personal experience) show progressive narrowing of a skin urethra due to chronic dermatitis caused by permanent contact with urine; this condition can cause bladder dysfunction with time due to chronic obstruction. Neourethra (one may presume made by skin) also sufficiently reduces space for implantation of prosthesis, especially of double cylinders. Sometimes the skin urethra is so hard that it palpably imitates malleable prosthesis.

Complication rate is high but acceptable for this highly sophisticated surgery. Generally speaking, the manuscript is useful for everyone who needs more information about what one can expect with erectile implants in neophallus.

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Editorial Comment on: Erectile Implants in Female-to-Male Transsexuals: Our Experience in 129 Patients

David J. Ralph, Giulio Garffa, A. Nim Christopher
St Peter's Andrology Centre, 145 Harley St, London W1G 6BJ, United Kingdom
dralph@andrology.co.uk

One of the goals of total phallic construction is the achievement of a rigidity that allows penetrative sexual intercourse. The insertion of penile prosthesis into a neophallus for transexualism is challenging due to the absence of the tunica albuginea, which constitutes a protective envelope for the prosthesis, anchoring it to the pubic bone and minimizing the risk of distal erosion. In this excellent paper, Hoebeke et al report on the largest series of 129 patients with good follow-up data for a mean of 30 mo [1].

With this vast experience over a 13-yr period, modifications to the devices and the techniques used

reflect the high complication and revision rates. Although the revision rate in this series is quite high, with 55.7% of patients requiring some form of revision surgery and an infection rate of 11.9%, these results can be expected due to the high complexity of the procedure. Similar complication rates have been reported by others [2–4].

Several lessons can be learned from this experience: One cylinder should be used wherever possible to improve cosmesis; use of a Dacron vascular graft should be limited to prevent cylinder leaks and infection; and life expectancy of the implant is only 50% at 4 yr. Because these patients are young and sexually active, all patients should be warned that multiple revisions may be necessary.

The authors are to be congratulated for this pioneering surgery in trying to find the gold standard approach to one of the most demanding areas of penile prosthesis surgery.

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